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Companywide	Program Requirements Document	For Additional Info: <a href="http://EDMS">http://EDMS</a>	Effective Date: 11/11/02
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Manual: 13A- Quality and Requirements Management Program Documents

Change Number: 93917

## 1. PURPOSE

Program Requirements Document (PRD) identifies requirements and responsibilities for ensuring that designs are defined, controlled, and verified. See Appendix A for requirements basis.

## 2. APPLICABILITY

This PRD applies to organizations involved in *design control* (see def.).

## 3. RESPONSIBILITY

### 3.1 Engineering Organizations

The Engineering organizations are responsible for:

- A. Establishing engineering organization policies and procedures for controlling design, engineering, *configuration management* (see def.), regulatory positions, and nuclear safety processes.
- B. Ensuring that engineering activities are executed in accordance with the requirements of this quality assurance (QA) PRD.
- C. Implementing appropriate *corrective actions* (see def.), up to and including stop work, when work is not in compliance with the applicable design control requirements.
- D. Determining the need for and controlling facility design and modifications.
- E. Assuring *design input* (see def.) documents, including functional requirements and other authorization basis documents, are developed.
- F. Evaluating environmental and safety impacts.
- G. Reviewing *design change* (see def.) documents, as required.
- H. Participating in peer/technical reviews, as required.
- I. Implementing configuration management for facilities, systems, and components under its control.

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- J. Assuring *design output* (see def.) documents are consistent with design inputs and authorization basis documents.
- K. Developing detailed design output documents.
- L. Maintaining alignment of design output documents with design input document requirements.
- M. Providing *technical support organization* (see def.) interface.
- N. Coordination of resources during the execution of a project.
- O. Successful turnover of the project to the user.
- P. Establishing inspection and test acceptance criteria.
- Q. Ensuring test and inspection plans are prepared.
- R. Approving test and inspection plans.

**3.2 Quality Assurance Organization**

The quality assurance organization is responsible for establishing the QA program requirements for design control.

**3.3 Cognizant Quality Engineer**

The *Cognizant Quality Engineer* (see def.) associated with the organization requesting or providing the design activities/documents is responsible for:

- A. Providing input, reviewing, and approving quality requirements for selected design documents, and subsequent changes.
- B. Approving inspection plans for quality *items* (see def.).
- C. Performing or coordinating performance of required independent inspections.
- D. Approving test and inspection plans.

**3.4 Technical Support Organization**

The Technical Support Organization is responsible for:

- A. Developing functional acceptance criteria.
- B. Accepting design input documents.

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- C. Developing facility/system descriptions.
- D. Preparing technical baseline documents and approving changes thereto.
- E. Maintaining alignment of design output documents with design input document requirements.
- F. Participating in technical reviews, as required.
- G. Assisting engineering in performing the activities listed.

**4. REQUIREMENTS****4.1 Companywide Applications**

The requirements identified in this subsection (4.1) apply to the entire company unless exempted by INT-17, QA PRD Introduction, Subsection 2.

**4.1.1 Basic**

- 4.1.1.1 The design shall be defined, controlled, and verified. *[NQA-1-1997, Requirement 3, 100 1s; DOE/RW-0333P 3.1]*
- 4.1.1.2 Design inputs shall be specified, translated into design documents, and approved on a timely basis. *[NQA-1-1997, Requirement 3, 100 2s; DOE/RW-0333P 3.2.1.B]*
- 4.1.1.3 Design interfaces shall be identified and controlled. *[NQA-1-1997, Requirement 3, 100 3s; DOE/RW-0333P 3.2.9.A]*
- 4.1.1.4 Design adequacy shall be verified by individuals other than those who designed the item or *computer program* (see def.). *[NQA-1-1997, Requirement 3, 100 4s; DOE/RW-0333P 3.2.4.D.1s]*
- 4.1.1.5 Design changes shall be governed by control measures commensurate with those applied to the original design. *[NQA-1-1997, Requirement 3, 100 5s]*
- 4.1.1.6 Drawings, specifications, and other design output documents shall contain appropriate inspection and testing acceptance criteria. *[DOE/RW-0333P 3.2.2.I]*
- 4.1.1.7 Procurement, development, modification, maintenance, operation, use, and retirement of computer *software* (see def.) used in the design analysis and verification *process* (see def.) shall comply with the requirements of PRD-5092, 19.1 Software Quality Assurance. *[NQA-1-1997, Requirement 3, 800 and Subpart 2.7]*

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**4.1.2 Design Input**

- 4.1.2.1 Applicable design inputs shall be identified and documented and their selection reviewed and approved by those responsible for the design. *[NQA-1-1997, Requirement 3, 200 1s; DOE/RW-0333P 3.2.1.A]*
- 4.1.2.2 The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. *[NQA-1-1997, Requirement 3, 200 2s; DOE/RW-0333P 3.2.1.B]*
- 4.1.2.3 Design inputs based on assumptions that require confirmation shall be identified and controlled as the design proceeds. *[DOE/RW-0333P 3.2.1.D; NQA-1-1997, Requirement 3, 402(d)]*

**4.1.3 Interface Control**

- 4.1.3.1 Design efforts shall be coordinated among participating organizations and groups. *[DOE/RW-0333P 3.2.9.B]*
- 4.1.3.2 Design information transmitted across interfaces shall be documented and controlled. They shall identify the status of the design information or document provided, and identify designs or portions of designs that require further development, analysis, review, or approval. *[NQA-1-1997, Requirement 3, 700 1s; DOE/RW-0333P 3.2.9.D and 3.2.9.E]*
- 4.1.3.3 Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document. *[NQA-1-1997, Requirement 3, 700 2s; DOE/RW-0333P 3.2.9.F]*

**4.1.4 Design Process**

- 4.1.4.1 The responsible design organization shall prescribe and document the design activities on a timely basis and to the level of detail necessary to permit the *design process* (see def.) to be carried out in a correct manner, and to permit verification that the design meets requirements. *[NQA-1-1997, Requirement 3, 300(a) 1s; DOE/RW-10333P 3.2.2.A]*
- 4.1.4.2 Design documents shall adequately support facility design, fabrication, construction, and operation. *[NQA-1-1997, Requirement 3, 300(a) 2s; DOE/RW-0333P, 3.2.2.B]*

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- 4.1.4.3 Appropriate standards shall be identified and documented, and their selection reviewed and approved. *[DOE/RW-0333P 3.2.2.C]*
- 4.1.4.4 The design methods, materials, parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application. *[NQA-1-1997, Requirement 3, 300(b) 1s; DOE/RW-0333P 3.2.2.E]*
- 4.1.4.5 Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel. *[NQA-1-1997, Requirement 3, 300(b) 2s; DOE/RW-0333P 3.2.2.F]*
- 4.1.4.6 Design documents shall be sufficiently detailed as to purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject can understand the documents and *verify* (see def.) their adequacy without recourse to the originator. *[DOE/RW-0333P 3.2.2.G]*
- 4.1.4.7 The final design including drawings, specifications, and other design output documents shall *[NQA-1-1997, Requirement 3, 300(c)]*:
- A. Be relatable to the design input by documentation in sufficient detail to permit design verification. *[NQA-1-1997, Requirement 3, 300(c)(1)]*
  - B. Specify required inspections and tests and include or reference appropriate acceptance criteria. *[NQA-1-1997, Requirement 3, 300(c)(2)]*
  - C. Identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a *commercial grade item* (see def.) *characteristics* (see def.) of the item to be verified for acceptance and the acceptance criteria for those characteristics shall be documented. *[NQA-1-1997, Requirement 3, 300(c)(3) 1s and 300(c)(3) 2s; DOE/RW-0333P 3.2.2.H.1s]*

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- 4.1.4.8 Characteristics to be verified are those which provide reasonable assurance that the item will perform its intended function. If a commercial grade item, prior to its installation, is modified or selected by special inspection and/or testing to requirements that are more restrictive than the supplier's published product description, the component part shall be represented as different from the commercial grade item in a manner traceable to a documented description of the difference. *[NQA-1-1997, Requirement 3, 300(c)(3) 3s and 300(c)(3) 4s; DOE/RW-0333P 3.2.2.H.2s]*

**4.1.5 Design Analyses**

- 4.1.5.1 Design analyses shall be planned, controlled, and documented. Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator. *[NQA-1-1997, Requirement 3, 400; DOE/RW-0333P 3.2.3.A]*
- 4.1.5.2 Design analysis documents shall be legible and in a form suitable for reproduction, filing, and retrieval. *[DOE/RW-0333P 3.2.3.B]*
- 4.1.5.3 Calculations shall be identified by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date, or by other designators such that the calculations are traceable. *[DOE/RW-0333P 3.2.3.C]*
- 4.1.5.4 Documentation of design analyses shall include *[NQA-1-1997, Requirement 3, 402; DOE/RW-0333P 3.2.3.E]*:
- A. The objective of the analyses. *[NQA-1-1997, Requirement 3, 402(a); DOE/RW-0333P 3.2.3.E.1]*
  - B. Design inputs and their sources. *[NQA-1-1997, Requirement 3, 402(b); DOE/RW-0333P 3.2.3.E.2]*
  - C. Results of literature searches or other applicable background data (see def.). *[NQA-1-1997, Requirement 3, 402(c); DOE/RW-0333P 3.2.3.E.3]*
  - D. Assumptions and indication of those assumptions that must be verified as the design proceeds. *[NQA-1-1997, Requirement 3, 402(d); DOE/RW-0333P 3.2.3.E.4]*

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E. Identification of any computer calculation, including: identification of the computer type, computer program name, and revision; inputs; outputs; evidence of or reference to computer program verification; and the basis (or reference thereto) supporting application of the computer program to the specific physical problem. [NQA-1-1997, Requirement 3, 402(e); DOE/RW-0333P 3.2.3.E.5]

F. Identification of the originator, reviewer, and approver. [DOE/RW-0333P 3.2.3.E.6]

4.1.5.5 To the extent required in Subsection 4.1.5.6 of this PRD, computer program acceptability shall be preverified or the results verified with the design analysis for each application. Preverified computer programs shall be controlled in accordance with the requirements of this PRD. [NQA-1-1997, Requirement 3, 401 1s and 401 2s]

4.1.5.6 The computer program shall be verified to show that it produces correct solutions for the encoded mathematical *model* (see def.) within defined limits for each parameter employed. The encoded mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application. [NQA-1-1997, Requirement 3, 401(a) and 401(b)]

**4.1.6 Design Verification**

4.1.6.1 Design verification shall be performed to determine the adequacy of the design. Acceptable verification methods include, but are not limited to, any one or a combination of *design reviews* (see def.) , alternate calculations, and *qualification testing* (see def.). [DOE/RW-0333P, 3.2.4.A; NQA-1-1997, Requirement 3, 501]

4.1.6.2 The extent of the design verification shall be a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proved designs. [NQA-1-1997, Requirement 3, 500(d) 1s; DOE/RW-0333P 3.2.4.F]

4.1.6.3 Design verification shall be performed at appropriate times during the design process. [DOE/RW-0333P 3.2.4.E]

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- 4.1.6.4 Design verification shall be performed prior to releasing the design for procurement, manufacture, construction, or use by another organization except where this timing cannot be met, such as when insufficient data exists. In those cases, the unverified portion of the design shall be clearly identified and controlled. In all cases the design verification shall be completed prior to relying upon *structures, systems, and components* (SSCs; see def.), or computer programs to perform its function. [NQA-1-1997, Requirement 3, 500(b) 1s, 500(b) 2s, and 500(b) 3s; DOE/RW-0333P 3.2.4.E.1 and 3.2.4.E.2]
- 4.1.6.5 Where the design has been subjected to a verification in accordance with this PRD, the verification process need not be duplicated for identical designs. However [NQA-1-1997, Requirement 3, 500(d) 2s and 500(d) 3s; DOE/RW-0333P 3.2.4.G]:
- A. The applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. [NQA-1-1997, Requirement 3, 500(d) 3s; DOE/RW-0333P 3.2.4.H.1]
  - B. Known problems affecting the standard or previously proven designs and their effects on other features shall be considered. [NQA-1-1997, Requirement 3, 500(d) 4s; DOE/RW-0333P 3.2.4.H.2]
  - C. The original design and associated verification documentation shall be referenced in records of subsequent application of the design. [NQA-1-1997, Requirement 3, 500(d) 5s; DOE/RW-0333P 3.2.4.H.3]
- 4.1.6.6 If the design is modified to resolve verification findings, the modified design shall be verified prior to release for use. [NQA-1-1997, Requirement 3, 500(c); DOE/RW-0333P 3.2.7.F]
- 4.1.6.7 Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design, but who may be from the same organization. [NQA-1-1997, Requirement 3, 500(a) 3s; DOE/RW-0333P 3.2.4.D.1s]
- 4.1.6.8 The responsible design organization shall identify and document the particular design verification method(s) used. [NQA-1-1997, Requirement 3, 500(a) 1s]
- 4.1.6.9 The results of design verification shall be documented with the identification of the verifier clearly indicated. [NQA-1-1997, Requirement 3, 500(a) 2s; DOE/RW-0333P 3.2.4.C]



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**4.1.7 Design Reviews**

4.1.7.1 Design reviews shall be controlled and performed to ensure that

*[DOE/RW-0333P 3.2.5; NQA-1-1997, Requirement 3, 501.1]:*

- A. The design inputs were correctly selected and incorporated into the design. *[DOE/RW-0333P 3.2.5.A; NQA-1-1997, Requirement 3, 501.1(a) and 501.1(d)]*
- B. Assumptions necessary to perform the design activity are adequately described, reasonable, and where applicable, are identified as requiring confirmation as the design proceeds. *[DOE/RW-0333P 3.2.5.B; NQA-1-1997, Requirement 3, 501.1(b) 1s]*
- C. Where necessary, the assumptions are identified for subsequent reverifications when the detailed design activities are completed. *[NQA-1-1997, Requirement 3, 501.1(b) 2s]*
- D. Appropriate design methods and computer programs were used, when applicable. *[DOE/RW-0333P 3.2.5.C; NQA-1-1997, Requirement 3, 501.1(c)]*
- E. The design output is reasonable compared to design inputs. *[NQA-1-1997, Requirement 3, 501.1(e); DOE/RW-0333P 3.2.5.D]*
- F. The necessary design inputs for interfacing organizations are specified in the design documents or in supporting procedures or instructions. *[NQA-1-1997, Requirement 3, 501.1(f); DOE/RW-0333P 3.2.5.E]*
- G. Suitable materials, parts, processes, and inspection and testing criteria have been specified. *[NQA-1-1997, Requirement 3, 501.1(g) ]*

**4.1.8 Alternate Calculations**

4.1.8.1 Alternate calculations shall use alternate methods to verify the correctness of original calculations or analyses. The appropriateness of assumptions; input data used; and the computer program, its associated computer hardware and system software, or other calculation method used shall also be reviewed. *[NQA-1-1997, Requirement 3, 501.2; DOE/RW-0333P 3.2.6]*

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#### 4.1.9 Qualification Tests

- 4.1.9.1 If design adequacy is to be verified by qualification tests, the tests shall be in accordance with PRD-5082, 11.1 Test Control.  
*[DOE/RW-0333P 3.2.7.A]*
- 4.1.9.2 Qualification tests shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means.  
*[NQA-1-1997, Requirement 3, 501.3.1s and 501.3 2s; DOE/RW-0333P 3.2.7.C.1s and 3.2.7.D]*
- 4.1.9.3 Required tests shall be controlled under appropriate operating modes and environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and test criteria. *[NQA-1-1997, Requirement 11, 200(a) 3s; DOE/RW-0333P 3.2.7.C.2s]*
- 4.1.9.4 Test procedures shall include or reference the test *configuration* (see def.) and test objectives. Test procedures shall also include provisions for assuring that prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed. *[NQA-1-1997, Requirement 11, 300(a) 1s and 300(a) 2s; DOE/RW-0333P 3.2.7.B and 3.2.7.C.2s]*
- 4.1.9.5 Test results shall be documented and evaluated by a responsible authority to assure that they satisfy test requirements and conform with acceptance criteria. *[NQA-1-1998, Requirement 11, 100 3s and 500 1s; DOE/RW-0333P 3.2.7.E]*
- 4.1.9.6 When tests are being performed on models or mockups, scaling laws shall be established, reviewed, and approved.  
*[DOE/RW-0333P 3.2.7.G; NQA-1-1997, Requirement 3, 501.3 3s]*
- 4.1.9.7 The results of model test work shall be subject to error analysis, where applicable, before using the results in final design work.  
*[DOE/RW-0333P 3.2.7.H; NQA-1-1997, Requirement 3, 501.3 4s]*

#### 4.1.10 Design Change Control

- 4.1.10.1 Design changes shall be controlled according to the following requirements *[DOE/RW-0333P 3.2.8]*:

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- A. Changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities shall be justified and shall be subject to design control measures commensurate with those applied to the original design. *[NQA-1-1997, Requirement 3, 600(a) 1s; DOE/RW-0333P 3.2.1.C]*

These design control measures shall include provisions to evaluate the effect of the changes on the overall previously verified design and ensure that the design analyses for the item are still valid. The evaluation shall include facility configurations that occur during operation, maintenance, *test* (see def.), *surveillance* (see def.), and inspection activities. *[DOE/RW-0333P 3.2.8.B; NQA-1-1997, Requirement 3, 600(a) 2s and 600(a) 3s]*

- B. Reviews are to be performed by personnel of the same disciplines who approved the original design, and typically only if their areas are affected by the change. *[Company Imposed Requirement]*
- C. Changes from specified standards, including the reasons for change, shall be identified, approved, documented, and controlled. *[DOE/RW-0333P 3.2.2.D]*
- D. If an organization that originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization shall be designated. *[DOE/RW-0333P 3.2.8.C.1]*
- E. The design organization approving the design shall have demonstrated competence in the specific design area of interest, and have an adequate understanding of the requirements and intent of the original design. *[NQA-1-1997, Requirement 3, 600(a) 4s; DOE/RW-0333P 3.2.8.C.2]*

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- F. When a significant design change is necessary because of an incorrect design, the design process and design verification methods and implementing documents shall be reviewed and modified as necessary. These design deficiencies shall be documented in accordance with PRD-5087, 16.1 Corrective Action. Additionally, if the incorrect design causes constructed or partially constructed SSCs to be nonconforming, the affected items shall be controlled in accordance with PRD-5086, 15.1 Control of Nonconforming Items. *[NQA-1-1997, Requirement 3, 600(c); DOE/RW-0333P 3.2.8.D.1s, 3.2.8.D.2s and 3.2.8.D.3s]*
- G. Nonconformances to design requirements dispositioned *use-as-is* (see def.) or *repair* (see def.) shall be subject to design control measures commensurate with those applied to the original design. Required as-built records shall reflect the use-as-is or repair condition. *[NQA-1-1997, Requirement 15, 404 3s and 404 4s; DOE/RW-0333P 3.2.8.A]*
- H. Field changes shall be incorporated into affected design documents when such incorporation is appropriate, and when a field change is approved other than by revision to the affected design documents. *[DOE/RW-0333P 3.2.8.E; NQA-1-1997, Requirement 3, 600(b)]*
- I. Design changes that impact related implementing documents or training programs shall be communicated to organizations affected by the change. *[DOE/RW-0333P 3.2.8.F]*

**4.1.11 Configuration Management of Operating Facilities**

- 4.1.11.1 Procedures implementing configuration management requirements shall be established and documented at the earliest practical time prior to facility operation. These procedures shall include the responsibilities and authority of the organizations whose functions affect the configuration of the facility, including activities such as operations, design, maintenance, construction, licensing, and procurement. *[NQA-1-1997, Requirement 3, 601.1s and 601 2s]*
- 4.1.11.2 Configuration management requirements shall include measures to ensure changes that may affect the approved configuration are recognized and processed. *[NQA-1-1997, Requirement 3, 601.1]*

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- 4.1.11.3 The configuration shall be established and approved at the earliest practical time prior to the initial operation of the facility, and maintained for the life of the facility. *[NQA-1-1997, Requirement 3, 601.2]*
- 4.1.11.4 The configuration shall include, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test requirements, supplier manuals and instructions, operating and maintenance requirements, and other applicable sources. *[NQA-1-1997, Requirement 3, 601.3]*
- 4.1.11.5 Interface controls shall include the integration of activities of organizations that can affect the approved configuration. *[NQA-1-1997, Requirement 3, 601.4]*
- 4.1.11.6 Documentation shall identify the design bases and the approved configuration for the approved modes of operation. *[NQA-1-1997, Requirement 3, 601.5]*
- 4.1.11.7 Measures shall be established and implemented to assure that proposed changes to the configuration are evaluated for their conformance to the design bases. *[NQA-1-1997, Requirement 3, 601.6]*
- 4.1.11.8 The implementation sequence for approved configuration changes shall be reviewed to determine that the configuration conforms to the design bases. *[NQA-1-1997, Requirement 3, 601.7]*
- 4.1.11.9 Approval by the *design authority* (see def.) shall be required prior to implementation of a change to the design bases. *[NQA-1-1997, Requirement 3, 601.8]*
- 4.1.11.10 The configuration of the facility shall be documented in drawings, specifications, procedures, and other documents which reflect the operational status of the facility. The process utilized to control the current revision and issuance of these documents shall take into account the use of the document and the need for revision to support operation. *[NQA-1-1997, Requirement 3, 601.9 1s and 601.9 2s]*

**4.1.12 Software Design Control**

- 4.1.12.1 The software design process shall be documented, approved by the responsible design organization, and controlled. *[NQA-1-1997, Requirement 3, 801 1s]*

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- 4.1.12.2 The requirements of PRD-5092, 19.1 Software Quality Assurance, shall apply to computer software design control and shall be used instead of Sections 4.1.2, Design Input; 4.1.4, Design Process; 4.1.6, Design Verification; and 4.1.10, Design Change Control, in this PRD. *[NQA-1-1997, Requirement 3, 800]*

#### **4.1.13 Field Surveying** (see def.)

- 4.1.13.1 A permanent system of horizontal and vertical controls shall be established and maintained. *[DOE/RW-0333P, Supplement IV, IV.2.1.A]*
- 4.1.13.2 The system shall be used in accordance with implementing documents to obtain accurate location and relocation of designated features including locations of sample or data collection. *[DOE/RW-0333P, Supplement IV, IV.2.1.B]*
- 4.1.13.3 Pertinent survey documents shall be identified, maintained, and verified for completeness as the work progresses. *[DOE/RW-0333P, Supplement IV, IV.2.2]*

#### **4.1.14 Records**

- 4.1.14.1 All records designated in implementing documents as quality assurance records shall be controlled in accordance with PRD-5088, 17.1 Quality Assurance Records. *[Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements]*
- 4.1.14.2 Design documentation and records shall include not only final design documents, such as drawings and specifications and revisions to those documents, but also documentation which identifies the important steps in the design process, including sources of design inputs that support the final design. *[NQA-1-1997, Requirement 3, 900]*

#### **4.2 Specific Requirement for DOE/RW-0333P QARD Revision 10 Application**

This subsection (4.2) contains additional requirements from the QARD (DOE/RW-0333P, Revision 10) which are specific to the Spent Nuclear Fuel Program.

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**4.2.1 Interface Control**

- 4.2.1.1 Interface controls shall include the assignment of responsibility and the establishment of implementing documents among participating design organizations and groups for the review, approval, release, distribution, and revision of documents involving design interfaces. *[DOE/RW-0333P 3.2.9.C]*

**4.2.2 Design Analyses**

- 4.2.2.1 Computer software used to perform design analyses shall be developed or qualified, and used according to the requirements of PRD-5092, 19.1 Software Quality Assurance, and DOE/RW-0333P, Rev.10, Supplement I, Software. *[DOE/RW-0333P 3.2.3.D]*

**4.2.3 Design Verification**

- 4.2.3.1 In addition to reviewing completed design analyses and design output in accordance with PRD-5071, 2.1 Quality Assurance Program, Subsection 4.2.7 and the above consensus requirements, the specific design control requirements in this section shall be applied. *[DOE/RW-0333P 3.2.4]*
- 4.2.3.2 The particular design verification method shall be identified and its use justified. *[DOE/RW-0333P 3.2.4.B]*
- 4.2.3.3 Design verification shall be performed by competent individuals or groups other than those who performed the original design, but may be from the same organization. If necessary, this verification may be performed by the originator's supervisor provided *[DOE/RW-0333P 3.2.4.D.1s and 3.2.4.D.2s]*:
- A. The supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or the supervisor is the only individual in the organization competent to perform the verification. *[DOE/RW-0333P 3.2.4.D.1 and 3.2.4.D.2]*
  - B. The verification is not hastily and superficially done. *[DOE/RW-0333P 3.2.4.D.3]*
  - C. The determination to use the supervisor is documented and approved, in advance, with concurrence of the QA organization. *[DOE/RW-0333P 3.2.4.D.4]*

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- D. Changes in previously verified designs shall require reverification. Such verification shall include the evaluation of the effects of those changes on the overall previously verified design and on any design analysis upon which the design is based. [DOE/RW-0333P 3.2.4.1.1s and 3.2.4.1.2s]
- E. Changes shall be approved by the same affected groups or organizations that approved the original design documents. [DOE/RW-0333P 3.2.8.C]

**5. DEFINITIONS**

Refer to LST-199, Definitions, in the QA PRD Manual for the definitions of the following terms:

*characteristics*

*cognizant quality engineer*

*commercial grade item*

*computer program*

*configuration*

*configuration management*

*corrective action*

*data*

*design authority*

*design change*

*design control*

*design input*

*design output*

*design process*

*design review*

*field surveying*



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*item**model**process**qualification testing**repair**software**structures, systems, and components (SSCs)**surveillance**system engineer**technical support organization**test**use-as-is**verify***6. REFERENCES**

ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications

DOE/RW-0333P, Civilian Radioactive Waste Management Program, Quality Assurance Requirements and Description, Revision 10

**7. APPENDICES**

Appendix A, 3.1 Basis

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**APPENDIX A****3.1 Basis**

Source	Citation	Requirement	Comments
ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications, Requirement 3	100 1s	4.1.1.1	Consensus Requirement (CR)
NQA-1-1997, Requirement 3	100 2s	4.1.1.2	CR
NQA-1-1997, Requirement 3	100 3s	4.1.1.3	CR
NQA-1-1997, Requirement 3	100 4s	4.1.1.4	CR
NQA-1-1997, Requirement 3	100 5s	4.1.1.5	CR
NQA-1-1997, Requirement 3	200 1s	4.1.2.1	CR
NQA-1-1997, Requirement 3	200 2s	4.1.2.2	CR
NQA-1-1997, Requirement 3	300(a) 1s	4.1.4.1	CR
NQA-1-1997, Requirement 3	300(a) 2s	4.1.4.2	CR
NQA-1-1997, Requirement 3	300(b) 1s	4.1.4.4	CR
NQA-1-1997, Requirement 3	300(b) 2s	4.1.4.5	CR
NQA-1-1997, Requirement 3	300(c)	4.1.4.7	CR
NQA-1-1997, Requirement 3	300(c)(1)	4.1.4.7.A	CR
NQA-1-1997, Requirement 3	300(c)(2)	4.1.4.7.B	CR
NQA-1-1997, Requirement 3	300(c)(3) 1s and 300(c)(3) 2s	4.4.7.1.C	CR
NQA-1-1997, Requirement 3	300(c) (3) 3s and 300(c) (3) 4s	4.1.4.8	CR
NQA-1-1997, Requirement 3	400	4.1.5.1	CR
NQA-1-1997, Requirement 3	401 1s and 401 2s	4.1.5.5	CR
NQA-1-1997, Requirement 3	401(a) and 401(b)	4.1.5.6	CR
NQA-1-1997, Requirement 3	402	4.1.5.4	CR
NQA-1-1997, Requirement 3	402(a)	4.1.5.4.A	CR
NQA-1-1997, Requirement 3	402(b)	4.1.5.4.B	CR
NQA-1-1997, Requirement 3	402(c)	4.1.5.4.C	CR
NQA-1-1997, Requirement 3	402(d)	4.1.2.3	CR
NQA-1-1997, Requirement 3	402(d)	4.1.5.4.D	CR
NQA-1-1997, Requirement 3	402(e)	4.1.5.4.E	CR
NQA-1-1997, Requirement 3	500(a) 1s	4.1.6.8	CR
NQA-1-1997, Requirement 3	500(a) 2s	4.1.6.9	CR
NQA-1-1997, Requirement 3	500(a) 3s	4.1.6.7	CR

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Source	Citation	Requirement	Comments
NQA-1-1997, Requirement 3	500(b) 1s, 500(b) 2s and 500(b) 3s	4.1.6.4	CR
NQA-1-1997, Requirement 3	500(c)	4.1.6.6	CR
NQA-1-1997, Requirement 3	500(d) 1s	4.1.6.2	CR
NQA-1-1997, Requirement 3	500(d) 2s and 500(d) 3s	4.1.6.5	CR
NQA-1-1997, Requirement 3	500(d) 3s	4.1.6.5.A	CR
NQA-1-1997, Requirement 3	500(d) 4s	4.1.6.5.B	CR
NQA-1-1997, Requirement 3	500(d) 5s	4.1.6.5.C	CR
NQA-1-1997, Requirement 3	501	4.1.6.1	CR
NQA-1-1997, Requirement 3	501.1	4.1.7.1	CR
NQA-1-1997, Requirement 3	501.1(a)	4.1.7.1.A	CR
NQA-1-1997, Requirement 3	501.1(b) 1s	4.1.7.1.B	CR
NQA-1-1997, Requirement 3	501.1(b) 2s	4.1.7.1.C	CR
NQA-1-1997, Requirement 3	501.1(c)	4.1.7.1.D	CR
NQA-1-1997, Requirement 3	501.1(d)	4.1.7.1.A	CR
NQA-1-1997, Requirement 3	501.1(e)	4.1.7.1.E	CR
NQA-1-1997, Requirement 3	501.1(f)	4.1.7.1.F	CR
NQA-1-1997, Requirement 3	501.1(g)	4.1.7.1.G	CR
NQA-1-1997, Requirement 3	501.2	4.1.8.1	CR
NQA-1-1997, Requirement 3	501.3 1s and 501.3 2s	4.1.9.2	CR
NQA-1-1997, Requirement 3	501.3 3s	4.1.9.6	CR
NQA-1-1997, Requirement 3	501.3 4s	4.1.9.7	CR
NQA-1-1997, Requirement 3	600(a) 1s	4.1.10.1.A Para. 1	CR
NQA-1-1997, Requirement 3	600(a) 2s and 600(a) 3s	4.1.10.1.A Para 2	CR
NQA-1-1997, Requirement 3	600(a) 4s	4.1.10.1.E	CR
NQA-1-1997, Requirement 3	600(b)	4.1.10.1.H	CR
NQA-1-1997, Requirement 3	600(c)	4.1.10.1.F	CR
NQA-1-1997, Requirement 3	601 1s and 601 2s	4.1.11.1	CR
NQA-1-1997, Requirement 3	601.1	4.1.11.2	CR
NQA-1-1997, Requirement 3	601.2	4.1.11.3	CR
NQA-1-1997, Requirement 3	601.3	4.1.11.4	CR

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Source	Citation	Requirement	Comments
NQA-1-1997, Requirement 3	601.4	4.1.11.5	CR
NQA-1-1997, Requirement 3	601.5	4.1.11.6	CR
NQA-1-1997, Requirement 3	601.6	4.1.11.7	CR
NQA-1-1997, Requirement 3	601.7	4.1.11.8	CR
NQA-1-1997, Requirement 3	601.8	4.1.11.9	CR
NQA-1-1997, Requirement 3	601.9 1s and 601.9 2s	4.1.11.10	CR
NQA-1-1997, Requirement 3	700 1s	4.1.3.2	CR
NQA-1-1997, Requirement 3	700 2s	4.1.3.3	CR
NQA-1-1997, Requirement 3	800	4.1.1.7	CR
NQA-1-1997, Requirement 3	800	4.1.12.2	CR
NQA-1-1997, Requirement 3	801 1s	4.1.12.1	CR
NQA-1-1997, Requirement 3	900	4.1.14.2	CR
NQA-1-1997, Requirement 11	100 3s and 500 1s	4.1.9.5	CR
NQA-1-1997, Requirement 11	200(a) 3s	4.1.9.3	CR
NQA-1-1997, Requirement 11	300(a) 1s and 300(a) 2s	4.1.9.4	CR
NQA-1-1997, Requirement 15	404 3s and 404 4s	4.1.10.1.G	CR
NQA-1-1997, Subpart 2.7	All	4.1.1.7	CR
DOE/RW-0333P, Office of Civilian Radioactive Waste Management Program, Quality Assurance Requirements and Description, Revision 10	3.1	4.1.1.1	CR
DOE/RW-0333P	3.2.1.A	4.1.2.1	CR
DOE/RW-0333P	3.2.1.B	4.1.1.2	CR
DOE/RW-0333P	3.2.1.B	4.1.2.2	CR
DOE/RW-0333P	3.2.1.C	4.1.10.1.A Para. 1	CR
DOE/RW-0333P	3.2.1.D	4.1.2.3	CR
DOE/RW-0333P	3.2.2.A	4.1.4.1	CR
DOE/RW-0333P	3.2.2.B	4.1.4.2	CR
DOE/RW-0333P	3.2.2.C	4.1.4.3	CR
DOE/RW-0333P	3.2.2.D	4.1.10.1.B	CR
DOE/RW-0333P	3.2.2.E	4.1.4.4	CR
DOE/RW-0333P	3.2.2.F	4.1.4.5	CR

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Source	Citation	Requirement	Comments
DOE/RW-0333P	3.2.2.G	4.1.4.6	CR
DOE/RW-0333P	3.2.2.H.1s	4.4.7.1.C	CR
DOE/RW-0333P	3.2.2.H.2s	4.1.4.8	CR
DOE/RW-0333P	3.2.2.I	4.1.1.6	CR
DOE/RW-0333P	3.2.3.A	4.1.5.1	CR
DOE/RW-0333P	3.2.3.B	4.1.5.2	CR
DOE/RW-0333P	3.2.3.C	4.1.5.3	CR
DOE/RW-0333P	3.2.3.D.	4.2.2.1	Specific Requirement (SR)
DOE/RW-0333P	3.2.3.E	4.1.5.4	CR
DOE/RW-0333P	3.2.3.E.1	4.1.5.4.A	CR
DOE/RW-0333P	3.2.3.E.2	4.1.5.4.B	CR
DOE/RW-0333P	3.2.3.E.3	4.1.5.4.C	CR
DOE/RW-0333P	3.2.3.E.4	4.1.5.4.D	CR
DOE/RW-0333P	3.2.3.E.5	4.1.5.4.E	CR
DOE/RW-0333P	3.2.3.E.6	4.1.5.4.F	CR
DOE/RW-0333P	3.2.4	4.2.3.1	SR
DOE/RW-0333P	3.2.4.A	4.1.6.1	CR
DOE/RW-0333P	3.2.4.B	4.2.3.2	SR
DOE/RW-0333P	3.2.4.C	4.1.6.9	CR
DOE/RW-0333P	3.2.4.D.1 and 3.2.4.D.2	4.2.3.3.A	SR
DOE/RW-0333P	3.2.4.D.1s	4.1.1.4	CR
DOE/RW-0333P	3.2.4.D.1s	4.1.6.7	CR
DOE/RW-0333P	3.2.4.D.1s and 3.2.4.D.2s	4.2.3.3	SR
DOE/RW-0333P	3.2.4.D.3	4.2.3.3.B	SR
DOE/RW-0333P	3.2.4.D.4	4.2.3.3.C	SR
DOE/RW-0333P	3.2.4.E	4.1.6.3	CR
DOE/RW-0333P	3.2.4.E.1 and 3.2.4.E.2	4.1.6.4	CR
DOE/RW-0333P	3.2.4.F	4.1.6.2	CR
DOE/RW-0333P	3.2.4.G	4.1.6.5	CR
DOE/RW-0333P	3.2.4.H.1	4.1.6.5.A	CR
DOE/RW-0333P	3.2.4.H.2	4.1.6.5.B	CR
DOE/RW-0333P	3.2.4.H.3	4.1.6.5.C	CR

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Source	Citation	Requirement	Comments
DOE/RW-0333P	3.2.4.I.1s and 3.2.4.I.2s	4.2.3.3.D	SR
DOE/RW-0333P	3.2.5	4.1.7.1	CR
DOE/RW-0333P	3.2.5.A	4.1.7.1.A	CR
DOE/RW-0333P	3.2.5.B	4.1.7.1.B	CR
DOE/RW-0333P	3.2.5.C	4.1.7.1.D	CR
DOE/RW-0333P	3.2.5.D	4.1.7.1.E	CR
DOE/RW-0333P	3.2.5.E	4.1.7.1.F	CR
DOE/RW-0333P	3.2.6	4.1.8.1	CR
DOE/RW-0333P	3.2.7.A	4.1.9.1	CR
DOE/RW-0333P	3.2.7.B and 3.2.7.C.2s	4.1.9.4	CR
DOE/RW-0333P	3.2.7.C.1s and 3.2.7.D	4.1.9.2	CR
DOE/RW-0333P	3.2.7.C.2s	4.1.9.3	CR
DOE/RW-0333P	3.2.7.E	4.1.9.5	CR
DOE/RW-0333P	3.2.7.F	4.1.6.6	CR
DOE/RW-0333P	3.2.7.G	4.1.9.6	CR
DOE/RW-0333P	3.2.7.H	4.1.9.7	CR
DOE/RW-0333P	3.2.8	4.1.10.1	CR
DOE/RW-0333P	3.2.8.A	4.1.10.1.G	CR
DOE/RW-0333P	3.2.8.B	4.1.10.1.A Para 2	CR
DOE/RW-0333P	3.2.8.C	4.2.3.3.E	CR
DOE/RW-0333P	3.2.8.C.1	4.1.10.1.D	CR
DOE/RW-0333P	3.2.8.C.2	4.1.10.1.E	CR
DOE/RW-0333P	3.2.8.D.1s 3.2.8.D.2s and 3.2.8.D.3s	4.1.10.1.F	CR
DOE/RW-0333P	3.2.8.E	4.1.10.1.H	CR
DOE/RW-0333P	3.2.8.F	4.1.10.1.I	CR
DOE/RW-0333P	3.2.9.A	4.1.1.3	CR
DOE/RW-0333P	3.2.9.B	4.1.3.1	CR
DOE/RW-0333P	3.2.9.C	4.2.1.1	SR
DOE/RW-0333P	3.2.9.D and 3.2.9.E	4.1.3.2	CR
DOE/RW-0333P	3.2.9.F	4.1.3.3	CR

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DOE/RW-0333P, Supplement IV	IV.2.1.A	4.1.13.1	CR
DOE/RW-0333P, Supplement IV	IV.2.1.B	4.1.13.2	CR
DOE/RW-0333P, Supplement IV	IV.2.2	4.1.13.3	CR
PRD-5088, 17.1 Quality Assurance Records	All	4.1.14.1	Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements